



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/243,030	02/03/1999	MICHAEL GERARD TOVEY	23164-1001-D	1869
1444	7590	11/23/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			COOK, REBECCA	
624 NINTH STREET, NW				
SUITE 300			ART UNIT	
WASHINGTON, DC 20001-5303			PAPER NUMBER	
			1614	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/243,030	TOVEY, MICHAEL GERARD	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rebecca Cook	1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2003 and 04 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

Claims 36 and 38-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support is seen in the specification for the word "orally" in the proviso in claim 36 "provided that when the viral infection is a rhinoviral infection, the interferon is not delivered **orally** in a multiple or continuous dose" and applicant has not pointed out where said support can be found.

In claim 52 no support is found for the proviso "other than a rhinoviral infection." For subject matter to be excluded by proviso the specification must disclose that said matter can be excluded. In the instant specification there is no indication that the treatment of other viruses is preferred over the treatment of rhinovirus.

In view of the amendments to claim 38 and applicant's arguments, the earlier rejections under 35 USC 112, paragraph two are withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 37 is again rejected under 35 U.S.C. 103(a) as being unpatentable over 5,286,748 (Eby III) for the reasons given in the Paper of December 11, 2003.

Applicant argues that claim 37 requires greater than about  $30 \times 10^6$  IU of interferon. This is not persuasive. The recitation "greater than about" would include the amount disclosed in Eby, since "about" could be considerably less than the amount recited. Regarding the recitations "said oromucosal administration being in a manner which does not involve direct action of the interferon on virally infected cells and where the interferon does not enter the bloodstream," applicant recites a property that results from oromucosal administration, not a new method of use. It would be inherent that this would also occur in the method of Eby.

In view of the proviso to claim 36 the rejection over Eby is withdrawn. Said rejection will be made again if the claim is amended to overcome the rejection under 35 USC 112, paragraph one that is made above.

Applicant's arguments regarding a rejection under 35 USC 102 have been considered but are not persuasive, since the rejection over Eby was made under 35 USC 103 (a) and not 35 USC 102.

Claims 22-51 are again rejected and claims 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amgen for the reasons given in the Paper of December 11, 2003.

Claims 22-51 are again rejected and claims 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/21229 (Amgen) in view of CA 1,297,788 (Feinberg) for the reasons given in the Paper of December 11, 2003.

Applicant's argument that oral and nasally administered IFN-con disclosed in Amgen must enter the bloodstream to produce the effects observed for parenteral administration is not persuasive. Applicant recites a property that results from oromucosal administration, not a new method of use. It would be inherent that this would also occur in the method of Amgen. Furthermore, even if this were not inherent, data presented in the specification demonstrates that only INF- $\alpha$  is not absorbed into the bloodstream and only claims 27 and 43 recite INF- $\alpha$ .

**Action is Final**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook



Primary Examiner  
Art Unit 1614

November 18, 2004